DEC 23 2009

Special 510(k) Summary of Safety and Effectiveness: Modifications to the AVS® PL PEEK Spacer System

Proprietary Name:	AVS® PL PEEK Spacer System
Common Name:	Spinal Fixation Appliances
Proposed Regulatory Class:	Class II Intervertebral body fusion device 21 CFR 888.3080
Device Product Code:	MAX
For Information contact:	Kimberly Lane Regulatory Affairs Specialist 2 Pearl Court Allendale, NJ 07401 Telephone: (201) 760-8215 Fax: (201) 760-8415 Email: kimberly.lane@stryker.com
Date Summary Prepared:	November 30, 2009
Predicate Device	AVS® PL PEEK Spacers and DePuy AcroMed, Inc. Lumbar I/F Cage® with VSP Spine System: P960025 (i.e., Brantigan Cage)
Predicate Device Information	The subject AVS PL PEEK Spacers and the predicates AVS PL PEEK Spacers and DePuy's Lumbar I/F Cage (i.e., Brantigan Cage) share similar design features: • Hollow frame PEEK Implant • Lateral fenestrations • Serrations on the superior and inferior surfaces • Comparable heights, widths, and angles • Materials and mechanical testing results are similar between the subject device and the listed predicates.

Description of Device Modification	This Special 510(k) premarket notification is intended to introduce the same design modifications applied to the AVS® PL PEEK Spacers cleared under K080758, K082014 and K090816. Note that the AVS® PL PEEK Spacers may also be referred to as AVS® Plus or AVS® PL-UniLIF.
Intended Use	The Stryker Spine AVS® PL PEEK Spacers are intervertebral body fusion devices indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy. The AVS® PL PEEK Spacers are to be implanted via posterior approach. The AVS® PL PEEK Spacers are intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (i.e., posterior pedicle screw and rod systems).
Summary of the Technological Characteristics	Testing in compliance with FDA's June 12, 2007 "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" was performed for the AVS® PL PEEK Spacers and demonstrated substantially equivalent performance characteristics to the identified predicate device systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

DEC 23 2009

Stryker Corp.
% Stryker Spine
Ms. Kimberly Lane
2 Pearl Court
Allendale, New Jersey 07401

Re: K093704
Trade/Device Name: Stryker Spine AVS® PL PEEK Spacers
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: MAX
Dated: November 30, 2009
Received: December 1, 2009

Dear Ms. Lane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093704

Device Name: Stryker Spine AVS® PL PEEK Spacers

Indications For Use:

The Stryker Spine AVS® PL PEEK Spacers are intervertebral body fusion devices indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1.

DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy.

The AVS® PL PEEK Spacers are to be implanted via posterior approach.

The AVS® PL PEEK Spacers are intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (i.e., posterior pedicle screw and rod systems).

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093704